JUN - 5 2000

510(k) SUMMARY K000998

THE OPTION CLEANING AND DISINFECTING SYSTEM for NON-UV ABSORBING SOFT (HYDROPHILIC) CONTACT LENSES

1.	Submitted by:	Optisonic, Inc 399 S. Edgeware Rd, Unit 7 St. Thomas, Ont N5P 4R8 Canada
	Contact: Official agent	John M. Szabocsik, Ph.D. Szabocsik and Associates 203 N. Wabash, Ste 1200 Chicago, IL 60601 (312) 553-0828
2.	Date prepared:	May 25, 2000
3.	Device: Common Name Trade Name	 Contact Lens Care System OPTION Care System for non-UV absorbing soft (hydrophilic) contact lenses
4.	Classification	Class II (Performance Standards) 21 CFR 886.5928 Soft (hydrophilic) contact lens care system
5.	Substantial equivalence	This product is substantially equivalent to the currently marketed PuriLens System for Soft (hydrophilic) Contact Lenses
6.	Device description	The OptiOn Care System is a portable automatic electronic lens care system which is designed to clean and disinfect contact lenses through the use of ultrasonic energy, ultraviolet light waves and a non-preserved saline solution.
7.	Intended use	The OptiOn Cleaning and Disinfecting System is to be used to clean, disinfect and store soft (hydrophilic) contact lenses.

8. Comparison to predicate devices:

The unit uses ultrasonic energy to physically remove the organic and microbial contaminants that accumulate on contact lenses. Ultraviolet energy is used to reduce the viable microorganisms (disinfect). The predicate PuriLens system uses subsonic agitation to remove lens deposits and microorganisms and ultraviolet radiation of the surrounding storage solution for disinfection.

9. Preclinical testing

Disinfection efficacy testing included a modified stand alone test (with organic soil) and the Regimen test. Results from the modified stand alone test showed a greater than 5 log reduction for the bacteria and yeast, a log reduction of 2 or greater for the fungi and *B. pumilus*. The OptiOn System met the requirements for the regimen test for non-UV absorbing soft lenses. The system also was shown to be compatible with Group 1 and Group 4 lenses in 30 cycles of simulated use. The lens cups met the requirements of toxicological testing for Plastics for Ophthalmic Containers. The electrical units were shown to meet manufacturing specifications in terms of output for over 150 cycles.

10. Clinical testing

A clinical trial of 79 subjects, 51 test and 28 control, was conducted over 3 months. The OptiOn Care system was compared to a commercially available multipurpose solution, with both Group 1 and Group 4 lenses, worn on a daily wear schedule. No differences were noted in lens cleanliness between test and control. Lenses were recovered from the subjects at the end of the 3 month trial period, examined and analyzed for protein deposition. No significant differences were detected between test and control lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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OPTISONIC, Inc.
C/O John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 North Wabash Ave., Suite #1200
Chicago, IL 60601

Re: K000998
Trade Name: OptiOn Care System
Regulatory Class: II
Product Code: LPN
Dated: March 20, 2000
Received: March 23, 2000

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K000998

Device Name: OptiOn Care System

Indications For Use:

The OptiOn Care System is designed to clean and disinfect only hydrophilic, non-UV absorbing contact lenses through the use of ultrasonic energy and ultraviolet light waves. Sterile, non-preserved aerosol saline, only, is to be used with the OptiOn twelve minute contact lens care system. Usage of any product other than sterile, non-preserved aerosol saline may result in an incomplete cleaning process and/or lens discomfort. If using OptiOn in a foreign country, usage of a proper adaptor will ensure maximum safety and performance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

____Prescription Use OR X Over-the-Counter Use (Per 21 CFR 801.109)

Karen Waibonton

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000998

(Optional Format 3-10-98)